GUIDLELINES FOR AF (pH) SAMPLE SUBMISSION

Thank you for your inquiry to the California Department of Health Services' Food and Drug Branch (FDB) Botulism Control and Cannery Inspection Program regarding your interest in producing a new pH controlled acidified food (AF). The following procedures relate to products that will be evaluated to determine the need to be packed under pH control.

1. You must first submit samples to the State's consulting Laboratory for evaluation. This sample testing and evaluation is a free service. Please complete the form, "Request for pH Control" (pdf), in detail for each product evaluated. Use one form for each separate product you wish to have evaluated. Describe in detail your product formula and all ingredients, preparation methods and manufacturing procedure, including the batch formulation, temperatures, etc. Do not intermingle unit measurements for ingredients, such as weights in ounces and not in fluid ounces. It is preferable if you can list the percentage of each ingredient in the formula rather than the unit measurement. Send the completed form, along with two samples of each product to:

University of California Laboratory
For Research in Food Preservation
6363 Clark Avenue
Dublin, CA 94568-3097

2. You must prepare your food product according to your formula and pack the food into two separate containers of the type you plan to use to market the product. The sample should be prepared by the facility that will be processing the product. Be sure to mark the samples with the product name, your name and address, and date of preparation. You should keep a photocopy of the "Request for pH Control" (pdf) form on file for the licensing inspection at a later date. *If there are any changes in your formula or preparation procedure, you must re-submit samples and forms to the Laboratory for another evaluation.*

3. The evaluation will be completed within 4-6 weeks. The consulting Laboratory will send its recommendation to FDB, who will then advise you of the results and determination via an official letter. During this time, please **do not** call the U.C. Laboratory to find out the results for your product.

4. If your product is determined to be subject to "pH control" or FDB product release supervision, you are required to take several steps to produce the product commercially:

- You must submit a Cannery License Application and successfully meet the requirements of a new license inspection conducted by FDB.
- You must submit license fees and deposits required pursuant to the Health and Safety Code Section 112675.

- You must have a suitable production facility for manufacturing. A commercial kitchen is satisfactory. The facility must be equipped with a pH meter and appropriate buffers for standardization of the instrument. The sample submitted should be prepared at this facility.
- The licensed cannery must comply with the Good Manufacturing Practices (GMP) requirements pursuant to Title 21 Code of Federal Regulations Part 110.
- You must develop an appropriate record system and retain all records as required for all pH control products.
- You must develop a container coding system and apply the code to all containers produced.
- Once you are licensed and are ready to begin operations, you are required to notify FDB before you begin manufacturing any product that requires the FDB release for shipment. To routinely release product, an FDB investigator will arrange to inspect your facility and audit your records, conduct pH determinations on samples pulled from each batch produced, and release product that is below the maximum pH allowed.
- You are required to notify FDB whenever you need a release of product, whenever any spoilage is noted, or if any foodborne illness has been reported.
- No batches of products that are required to be produced under the Cannery Inspection Program can be sold or donated until they have been officially released by FDB. Violations of the law are subject to fines or imprisonment.
- Please note that the hourly inspection fees are charged for inspection and travel time for your facility. The canner will be billed on a monthly basis. As specified in law, the Cannery Inspection Board establishes the hourly rate for inspection on a quarterly basis. The current rates are in excess of $120 per Hour.
- All fish and seafood products produced in a licensed cannery must also meet the federal Hazard Analysis and Critical Control Point (HACCP) requirements before the products will be released by FDB.
- All products should be produced under supervision of a person who has attended a Better Process Control School as specified in 21 CFR 114.10.
- You are also responsible to register your facility and the products you produce with the U.S. Food and Drug Administration.

Upon the completion of the state contracted laboratory evaluation, if your product is not subject to “pH control” or FDB’s cannery inspection program, the processed food product must still be manufactured in a food processing facility registered with FDB’s Processed Food Registration Program (PFR). Please call (916) 650-6500 for PFR registration information and an application form.

Note (regarding sample submission to the U.C. Laboratory for evaluation): Your product formulation is protected under the law: State of California Health and Safety Code Section 110165 makes it unlawful for any person to use to his own advantage, or to reveal to any person other than to the director or officers or employees of this department, or to the courts when relevant in any judicial proceeding under this division, any information acquired under authority of this division concerning any method or process which as a trade secret is entitled to protection.